Again the CoA also considered the legislative purpose when considering the scope of an undertaking, and articulated that were the CMA not able to investigate outside of the UK, it would become "*largely toothless when confronting international cartels*".

## Implications

The CoA's judgment confirms that the CMA has the power to compel foreign businesses, even those without a "UK territorial connection", to provide information and documents upon request if relevant to an investigation. The CMA has evidently welcomed the CoA's judgment. Section 26 notices are a vital tool by which the CMA may carry out its investigations into allegedly anti-competitive practices, and the CMA's chief executive Sarah Cardell has expressed that the judgment "*strengthens the CMA's ability to investigate, enforce against and deter any anti-competitive conduct that harms consumers, businesses and markets in the UK*". In fact, the judgment itself highlights that it would create "*a perverse incentive for conspirators to move offshore to organise cartels directed at harming the United Kingdom market*" were the CMA not be able to gather information from overseas.

In practice, the judgment simply gives earlier judicial conformation of a position that will be confirmed legislatively later this year: the Digital Markets, Competition and Consumers Bill (DMCC Bill) expressly provides for the CMA's information gathering powers to extend to foreign persons. That Bill will also increase the fines that the CMA can impose for non-compliance: up from of £30,000 (as well as daily fines of £15,000) to 1% of a business' annual worldwide turnover (and daily penalties up to 5% of daily worldwide turnover).

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## ANTI-COMPETITIVE PRACTICES

*Competition and Markets Authority—Statement—enforcement—restrictive business practices—medicine manufacturers—price-sharing—combination therapy treatment—negotiation framework—investigation not prioritised*

Anti-competitive practices; Competition and Markets Authority; Negotiations; NHS; Pharmaceutical services; Statements

### CMA to deprioritise enforcement action against competing combination therapy treatment providers in negotiation with the NHS

The United Kingdom's (UK) Competition and Markets Authority (the "CMA") has released a statement (the "Statement") confirming that it will not prioritise enforcement action under the Competition Act 1998 (CA98) against price-sharing between competing medicine manufacturers who have followed a new combination-therapy-specific negotiation framework proposed by the Association of the British Pharmaceutical Industry (the "ABPI"). The goal of the ABPI framework and the CMA's Statement is to encourage companies to negotiate agreements that would make new combination therapies available to UK patients.[1]

## Background

Combination therapy is where two separate medicines (typically, a 'backbone' treatment and an 'add-on' treatment) are used in combination to treat disease. According to the ABPI, combination treatments often generate better health outcomes and can have broad potential use-cases. By way of example, over half of ABPI members' oncology pipeline currently consists of combination therapies.

[1] Competition and Markets Authority (CMA), "Combination therapies: prioritisation statement" (17 November 2023), available at: *https://www.gov.uk/government/publications/combination-therapies-prioritisation-statement*.

However, the ABPI has identified that suppliers face significant difficulty in reaching the required 'cost-effectiveness' threshold to obtain the necessary recommendation from the relevant UK health technology assessment ("HTA") agency for deployment in the UK National Health System ("NHS").

In England, Wales, and Northern Ireland the relevant HTA is the National Institute for Health and Care Excellence ("NICE"), and in Scotland, it is the Scottish Medicines Consortium. NICE and NHS England ("NHSE") confirmed to the CMA that, since 2017, 50% of combination therapy appraisals for cancer treatment were terminated or not found to be 'cost effective'.

According to the ABPI and the CMA, this has resulted in many companies withdrawing from efforts to supply combination therapy treatments to the NHS, resulting in "reduced patient access to innovative treatments for serious diseases, and potentially a discouraging of investment in research and development in this area in the UK".[2]

Following engagement with the CMA, NICE and NHSE, the ABPI has proposed a new negotiating framework to resolve these issues by better facilitating information exchange between parties with a view to allowing the supply combination therapies to the NHS at a "cost effective" price. However, this framework risked raising potential competition law concerns, necessitating the Statement by the CMA to make it effective.

## The CMA's new position on combination therapies

The Statement confirms that the CMA will not prioritise the investigation of commercial negotiations and any subsequent agreements that are carried out according to the negotiation framework, where particular market features are present and certain conditions are met, to support the ABPI's negotiation framework.

Under the ABPI's proposed negotiation framework, a commercial agreement between companies supplying backbone and add-on treatments will be negotiated. This entails the exchange of pricing information and the agreeing of an amount per patient to be paid to the add-on supplier when a backbone medicine is supplied as part of the combination therapy.

However, aspects of the ABPI Negotiating Framework appeared liable to fall foul of UK competition law. It is well-established that the exchange of competitively sensitive information between actual or potential competitors, and commercial agreements, to the extent that any involve coordination on the price of a component medicine, may breach UK competition law under Chapter I of the CA98.

Therefore, the CMA has stated that it will not prioritise investigating either exchanges of information made under the ABPI framework or any subsequent agreements for the payment of contribution payments entered into by component medicine manufacturers, provided the five following circumstances are present:

1. The relevant component medicines to the combination therapy have been evaluated by the relevant UK HTA agency and a confidential net price (the "CNP") has been agreed for each between the supplier and the NHS, such that the clinician is free to prescribe them.
2. The negotiations between the component medicine suppliers and associated exchanges of information have been carried out according to the new ABPI negotiation framework in a good faith attempt to reach an agreement with a view to making a combination therapy available to NHS patients;

[2] CMA, "Combination therapies: prioritisation statement" (17 November 2023), para.2.12.

3. The information exchanged between the component medicine manufacturers is limited to what is permitted by the negotiation framework,[3] public information, or any information that is reasonably necessary for the component suppliers to agree the contribution payments. The CMA makes clear that the CNP is not within the scope of the permitted information exchange;
4. The terms of any agreement reached between the component suppliers are directly related and necessary for the calculation or operation of the contribution payments that have been agreed according to the negotiation framework. Any agreement to fix prices or to go beyond seeking to obtain reimbursement approval for a combination therapy is excluded from the ambit of the Statement; and
5. The manufacturers involved implement measures to ensure that information exchanged between them as part of the commercial negotiations or as part of any subsequent agreement are not disseminated more widely than necessary and are not used for any other purposes.[4]

The CMA's decision to deprioritise enforcement is justified on the rationale that the benefits that the reduced scrutiny and the new negotiation framework are intended to have on the supply and research into combination therapies in the UK outweigh the "limited scope for the exchange of information under the negotiation framework to lead to higher prices to the NHS or poorer patient outcomes".[5]

The CMA views: (i) the CNP; (ii) the new negotiation framework; and (iii) the fact that clinician decision-making in prescribing new medicines is primarily driven by a medicine's clinical effectiveness rather than price competition between suppliers, as sufficient limiting factors to mitigate the negative impact that the exchange of information may have for patients.[6]

## Conclusion

The CMA has recognised the medical benefits to be gained for patients from permitting otherwise potentially non-compliant behaviours from medicines suppliers, in order to allow them to collaborate on combination therapies and find pricing arrangements that work commercially while also meeting the UK HTA's cost effectiveness tests.

However, looking forward, the CMA acknowledges in the Statement that the new negotiation framework is "unlikely to be the 'last word' on the matter of bringing combination therapies to market".[7] It remains to be seen whether the Statement will give medicines' companies sufficient comfort in an environment where they must self-assess their compliance with competition law and face the consequences of any errors in that self-assessment. Accordingly, the CMA's approach may continue to evolve in the future as it continues to seek ways to encourage the growth of combination therapy treatments and research in the UK.

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[3] See: the Statement para.4.2-4.4.
[4] CMA, "Combination therapies: prioritisation statement" (17 November 2023), para.5.2.
[5] CMA, "Combination therapies: prioritisation statement" (17 November 2023), para.5.4.
[6] CMA, "Combination therapies: prioritisation statement" (17 November 2023), para.5.4 (a-c) and 5.5.
[7] CMA, "Combination therapies: prioritisation statement" (17 November 2023), para.5.9.